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**Review of the Psoriatic Arthritis working group at OMERACT 12: a report from the
GRAPPA 2014 annual meeting**

W. Tillett

L. Eder

N. Goel

M. deWit

A. Ogdie

AM Orbai

W. Campbell

O. FitzGerald

N. McHugh

D. Gladman

V. Strand

P. Mease

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Name and address of corresponding author

W. Tillett

Royal National Hospital for Rheumatic Diseases,

Bath,

BA11RL,

UK

w.tillett@nhs.net

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Abstract

The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) psoriatic arthritis 'Outcome Measures in Rheumatology'(OMERACT) working group presented a review of the progress made at the 2014 OMERACT meeting. At OMERACT members of the working group presented work from the Patient Involvement in Outcome Measures for Psoriatic Arthritis (PIOMPSA) group to improve the incorporation of patient research partners in psoriatic arthritis outcomes research, the results of discussions within the OMERACT breakout groups and finally the voting results. OMERACT meeting participants endorsed the need to update the psoriatic arthritis core set according to the Filter 2.0 framework. The workshop breakout group discussions identified opportunities the core set revision would allow, including the potential of consolidating existing redundancy within the core set, improved incorporation of the patient perspective and the possibility of including disease impact such as fatigue in to the inner circle. The GRAPPA working group has now set out a program of research to update the core set with the aim of seeking endorsement at OMERACT 2016.

Introduction

The psoriatic arthritis (PsA) core set for outcome measures to be used in randomized controlled trials (RCTs) and longitudinal observational studies was endorsed at Outcome Measures in Rheumatology (OMERACT) 8 in Malta.¹ Considerable work within the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) has been undertaken over the last eight years to develop appropriate individual and composite responder indices to capture disease activity.^{2, 3} At the OMERACT 10 meeting in 2012 it became clear that much of this work had been undertaken with little or no incorporation of the patient perspective. Incorporation of the patient perspective through meaningful, ongoing inclusion of patient research partners throughout the outcome measure development and domain selection process has acknowledged benefits. The role of patients in outcome research is embedded at the heart of the OMERACT process.^{4, 5} Prior examples of the benefits of this approach include the ability to determine the minimum clinically important differences (MCID) in patient reported outcomes, development of definitions of remission and flare and inclusion of fatigue and participation to the “core set” in rheumatoid arthritis.^{6, 7} A number of initiatives on both sides of the Atlantic are underway to firmly embed incorporation of the patient perspective in wider health research. The National Institutes of Health (NIH) has established the Patient Centered Outcomes Research Institute (PCORI) project, the National Institute of Health Research (NIHR) in the United Kingdom has convened the INVOLVE group to promote patient involvement in the National Health Service (NHS) and the European League Against Rheumatism (EULAR) has published recommendations for the inclusion of the patient perspective in research.⁸ At this GRAPPA annual meeting the psoriatic arthritis OMERACT working group presented a summary of the work of the PIOMPSA group over the last two years, the results of the breakout group discussions and attendee voting at

OMERACT 12 and a potential roadmap towards endorsement of a revised core set OMERACT 13 in 2016.

Presentations

The OMERACT 12 Psoriatic Arthritis working group overview

Dr Niti Goel introduced the PsA OMERACT working group; comprised of two fellows, four co-chairs, three patient research partners, one member of the OMERACT executive for liaison and two additional GRAPPA member attendees (see acknowledgments). The PsA workshop consisted of presentations of the work undertaken since OMERACT 10 including the Patient Outcome Measures for Psoriatic Arthritis (PIOMPSA) initiative,⁹ the Psoriatic Arthritis Impact of Disease (PsAID) study¹⁰ and the progress made towards development of composite disease activity measures.² The presentations were followed by discussion in breakout groups on the need to update the PsA core set and what revisions should be considered. Results for the breakout group were presented at the plenary followed by voting (report in press).¹¹

Review of the patient involvement initiative- PIOMPSA

The PIOMPSA effort was initiated in 2012 to improve incorporation of the patient perspective in PsA outcomes research within GRAPPA. The first meeting in Dublin, Ireland included equal numbers of rheumatologists and patient research partners and efforts have been made to preserve this balance to give patient research partners an equal voice at the proceedings.⁹ The PIOMPSA group discussed the relative lack of patient input in the development of the PsA core-set and outcome measure development and undertook a systematic literature review to define levels of patient involvement thus far together with a roadmap to enhance integration of patient perspectives in future research in PsA. The group identified a potential need to revise the

existing PsA core set. This was primarily to ensure incorporation of patient involvement in the domain selection and prioritisation but additionally to incorporate the considerable research progress from 2006 onward which could inform revision of the domains constructs including;

- The 68/66 (tender/swollen) joint count having been identified as the optimal joint count for PsA assessment in clinical trials.¹²
- Tools to assess fatigue, enthesitis, dactylitis and the measurement of axial disease haing been developed and tested.^{13, 14, 15}
- The Psoriasis Activity and Severity Index (PASI) having been shown to be reliable when performed by rheumatologists or dermatologists.¹⁶

Updating the core set in light of these research findings would allow patient representation and an opportunity for movement or incorporation of domains important to patients such as fatigue, dactylitis and participation (work/ leisure activities) that were not previously included.^{9, 17} Dr Goel summarised with an acknowledgment that the patient research partner role within GRAPPA needed to be formalised through the work done of the Building Bridges initiative.

Update of the PsA core set, breakout group discussion and voting

Dr Tillett reviewed the results of the OMERACT 12 breakout discussions and voting. The existing PsA core set, endorsed at OMERACT 8 in 2006, was reviewed (figure 1)¹ and compared with the new OMERACT filter 2.0.¹⁸ The new structure encourages researchers to consider domains within four ‘core areas’: pathophysiological manifestations, life impact, resource use and death. (figure 2).¹⁸ Domains are then placed within concentric spheres by decreasing importance and/or availability of applicable instruments and finally for the research agenda. The core (central) sphere should contain at least one domain of each core area (pathophysiological

manifestations, life impact, resource use and death). The middle sphere could contain a choice of additional domains dependent on the individual study question and the final outer sphere reserved for additional domains of interest in the research agenda. Participants at the OMERACT workshop breakout groups were given a copy of the existing PsA core set and asked to consider the need for its revision and if so what changes to consider.

Feedback from the breakout groups identified a number of themes. There was general agreement that there was a need to revise the PsA core set and this would present opportunities to improve the existing core set. Within the ‘core area’ of ‘pathophysiology’ there was considered to be an opportunity to amend existing redundancy. An umbrella term such as ‘inflammatory musculoskeletal disease’ for arthritis, enthesitis, dactylitis and axial disease could be considered. ‘Psoriasis activity’ may be considered as an encompassing term for skin and nail disease and ‘biomarkers’ for acute phase reactants. ‘Life impact’ concepts emerging from the breakout discussions included a strong message to retain pain, health related quality of life (HRQOL), function and patient global in the core set while adding fatigue which attendees noted had also been ranked highly in the PsAID study.¹⁰ There was debate regarding the potential overlap of domains captured in the patient global measure as well as fatigue. There was recognition of the increasing evidence that it is legitimate to move items like dactylitis¹⁹, fatigue²⁰ and enthesitis²¹ from former positions in the second circle to higher prioritization in the inner circle, especially as tools had been developed and tested since the initial core set creation to evaluate these.

The proposal to revise the PsA core set was strongly endorsed with a 100% vote by the OMERACT workshop participants and was notably the first time a unanimous vote had been achieved within OMERACT. The PsA core set will therefore be the first to undergo revision

using the OMERACT Filter 2.0. Consensus was also achieved on retaining the patient global within the core set (endorsed with 70% vote) as well as adding fatigue (endorsed with 72% vote).

Conclusion

At the OMERACT 12 PsA workshop there was unanimous endorsement for the need to update the PsA core set. The results of the OMERACT breakout group discussions highlighted opportunities to involve patients as well as add, move or merge existing domains to improve existing redundancy. Work over the next two years will focus on the revision of the PsA core set according to the filter 2.0 with the aim of seeking endorsement at OMERACT 13 in 2016.

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The OMERACT working group:

Co-chairs: Oliver FitzGerald, Dafna Gladman, Philip Helliwell, Philip Mease

OMERACT liaison: Vibeke Strand

Fellows: William Tillett, Lihi Eder

Patient Research Partners: Maarten deWit, Ina Campbell, Niti Goel

GRAPPA attendees: Alexis Ogdie, Anna-Maria Orbai

Conflicts of Interest

The authors declare no conflicts of interest relating to this manuscript.

Figure 1

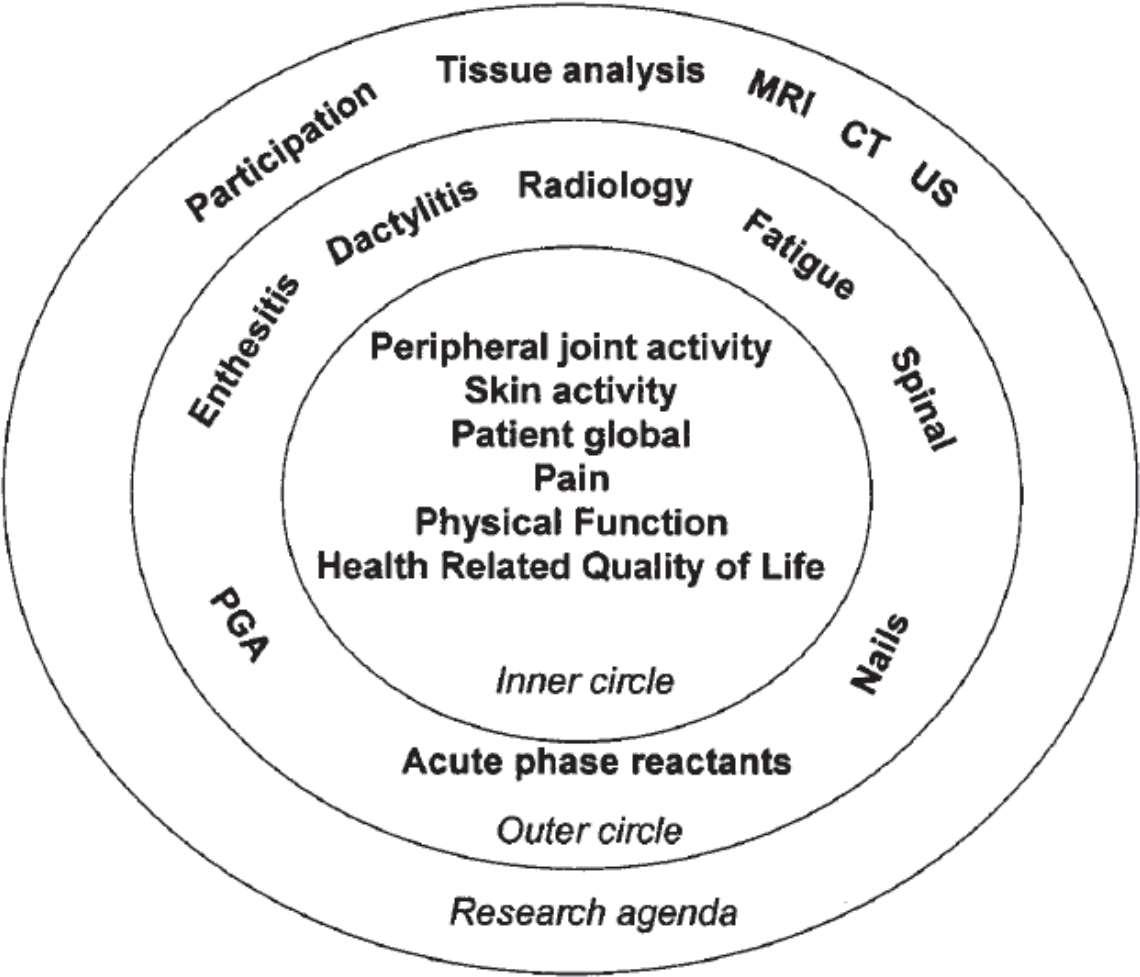
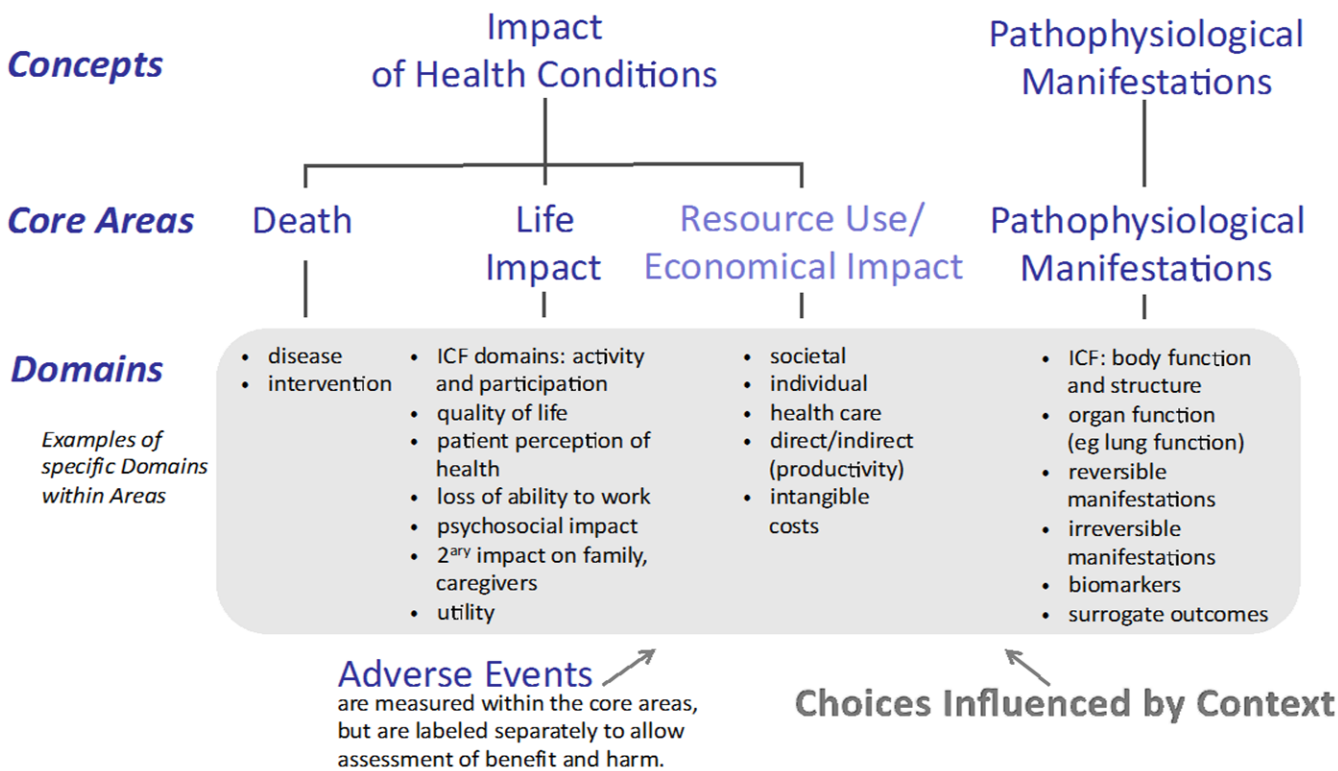


Figure 1. Domains for PsA. PGA: physician global assessment, MRI: magnetic resonance imaging, CT: computed tomography, US: ultrasound.

Domains for PsA (duplicated with kind permission)¹

Figure 2



Conceptual framework for core areas (duplicated with kind permission)¹⁸.

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